UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

LOUISIANA WHOLESALE DRUG CO., INC.,	)	Civil Action No. 07-cv-7343 (HB)
Plaintiff,	)	Hon. Harold Baer, U.S.D.J.
	)	ECF CASE
v.	)	
SANOFI-AVENTIS, SANOFI-AVENTIS U.S., LLC and AVENTIS PHARMACEUTICALS, INC.,	)	
Defendants.	)	

DEFENDANTS SANOFI-AVENTUS US LLC AND AVENTIS PHARMACEUTICALS, INC.'S REPLY MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF THEIR MOTION TO DISMISS THE COMPLAINT FOR FAILURE TO STATE A CLAIM

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In its complaint (the "Complaint") and again in its Opposition (the "Opposition") to Aventis' Motion to Dismiss the Complaint (the "Motion"), Louisiana Wholesale has completely divorced the relief Aventis requested in its March 31, 2005 citizen petition from the regulatory framework in which the Generic Manufacturers' abbreviated new drug applications ("ANDAs") and the citizen petition arose. Remarrying them with that framework and the administrative record surrounding it, there is no doubt that the citizen petition is First Amendment petitioning activity immune from antitrust liability; that Louisiana Wholesale's speculative and derivative claim does not provide it standing to pursue a Sherman Act cause of action; and that Louisiana Wholesale's self-serving market definition is patently deficient.

I. Louisiana Wholesale Has Failed to Demonstrate That Aventis Should Be Stripped of *Noerr-Pennington* Immunity for Its Petitioning Conduct

ANDAs are essentially copycat applications that rely on a branded manufacturer's new drug application ("NDA"). Specifically, ANDAs must provide the same active ingredient, dosage form, strength, route of administration, and labeling as the pioneer drug. 21 U.S.C. § 355(j)(2)(A). Thus, the Generic Manufacturers could not avail themselves of the ANDA pathway for leflunomide unless they (1) utilized a 100mg loading dose (since Arava and the clinicial studies supporting it employ a 100mg loading dose) or demonstrated that one 100mg tablet was bioequivalent to five 20mg tablets (as the FDA had asked Aventis to do when it sought to modify its own loading dose); and (2) referenced the 100mg loading dose in their label (just as Aventis does in the Arava label). Aventis' citizen petition simply asked the FDA to apply these requirements to the Generic Manufacturers. The fact that the FDA chose a different remedy—namely, requiring the Generic Manufacturers to reference *Arava*'s 100mg loading dose in their labels—did not undermine the legitimacy of Aventis' citizen petition, which is entitled to *Noerr-Pennington* immunity as a matter of law.

The FDA's denial of the petition does not end the Court's inquiry about the scope of First Amendment protection afforded to Aventis. In response to Aventis' specific concern that the 100mg loading dose should not be omitted from the label or substituted by five 20mg tablets without additional bioequivalence testing, the FDA declared that it would permit a "generic leflunomide product that refers in its labeling to a 100mg tablet (which is available from Aventis) as the loading dose," Motion Exh. 1 at 8, thereby rendering Aventis' concerns moot. The fact that the FDA identified a different remedy in response to the petition did not undercut its legitimacy or render it objectively baseless. Louisiana Wholesale's exclusive emphasis upon the remedy, without regard to the merits, is contrary to the law and makes no sense.

First, the objective merit of a claim must be examined by reference to the claim as a whole, not just the remedy or ultimate outcome. *See, e.g., Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 61 n.5, 62-63 (1992) (holding that petitioning conduct is objectively reasonable if "there is a chance that [a] claim may be held valid," and warning courts to "resist the understandable temptation to engage in *post hoc* reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation") (citations omitted). Moreover, Louisiana Wholesale completely ignores the rule, discussed in the Motion at 11-12, that a petition cannot be objectively baseless even if its success is limited. *See, e.g., Potters Med. Ctr. v. City Hosp. Ass'n*, 800 F.2d 568, 578-79 (6th Cir. 1986) (finding "relative success"); *In re Circuit Breaker Litig.*, 984 F. Supp. 1267, 1274 (C.D. Cal. 1997) (noting success only on some issues in case). These cases are flatly inconsistent with Louisiana Wholesale's unsupported assertion that the FDA's adoption of a different remedy resolves the question of the petition's objective merit.[1]

[1] Louisiana Wholesale claims that Aventis should have known that the Generic Manufacturers could refer to a loading dose manufactured by another company. Opp'n at 10. While it does not dispute the fact that ANDAs are confidential, *see* 21 C.F.R. §§ 314.430(b) and (d), Louisiana Wholesale does not explain how Aventis *could have known* what the Generic Manufacturers were proposing. And, it apparently was not clear to at least one of the

Louisiana Wholesale's apparent belief that asking for the "wrong" remedy strips a party of its antitrust immunity would lead to the absurd conclusion that the citizen petition would have been immune from antitrust liability if only Aventis had anticipated the "right" remedy and appended it to the petition. Such a request would not have affected any delay allegedly occasioned by the filing of the citizen petition.[2] Nothing in law or logic compels the "sham" analysis to turn on such a nonsensical and immaterial proposition.[3]

Louisiana Wholesale also fails to explain how a petition could possibly be objectively baseless if it merely requests evenhanded application of existing administrative rules. Instead, it asserts that *Potters Medical Center*, *see* Motion at 11-12, "is inapplicable" because the government solicited comments in that case and the petitioner enjoyed the support of other petitioners and agencies. Opp'n at 14. But the rule enunciated in *Potters Medical Center*—that there is an objective basis for a petition seeking to require another entity to "to comply with the same regulations" governing previous applicants, 800 F.2d at 579—did not turn on who initiated the petition or how many people lined up behind it.

Finding no support in the law for its arguments, Louisiana Wholesale contends that Aventis was asking the FDA to impose higher standards on the Generic Manufacturers than the

(continued…)

Generic Manufacturers that it could refer to the Arava loading dose in its label, as Kali Laboratories proposed that remedy to the FDA (without citing any support or precedent) when it responded to the citizen petition. *See* Motion Exh. 3 at 2.

[2] This is especially true since the administrative record clearly shows that the Generic Manufacturers were actively and repeatedly amending their ANDAs while the citizen petition was pending. Although the record does not indicate whether those amendments were intended to address concerns raised in the citizen petition or some other fundamental flaws, it is clear that the FDA was not yet prepared to approve the ANDAs anyway.

[3] Louisiana Wholesale characterizes a selective and therefore misleading citation from Aventis' October 3, 2007 letter to the Court as an admission of objective baselessness. Opp'n at 12. This is pure nonsense. In its letter, Aventis stated that a "reasonable litigant"—and especially one who lacked knowledge of an ANDA's contents—"would certainly expect the FDA to hold generic manufacturers to the same standards imposed on the NDA holder, either by requiring reference to a 100mg loading dose or by demonstrating the bioequivalence of five 20mg tablets to a 100mg tablet." Opp'n Exh. 2 at 4. The whole point of the citizen petition was to ask the FDA to take into account safety and efficacy concerns about the form of the 100mg loading dose, and to require the Generic Manufacturers to include the 100mg loading dose on the same terms and conditions the FDA had imposed upon Aventis years before.

FDA imposed on Aventis. Opp'n at 14. That is plainly not the case. The clinical trials upon which Aventis' NDA relied for its 20mg and 10mg tablets included a 100mg loading dose; thus, to the extent the Generic Manufacturers sought to rely on Aventis' safety and efficacy data for their own 20mg and 10mg tablets their labeling would have to refer to a 100mg loading dose. 21 U.S.C. § 355(j)(2)(A)(v). Aventis' request for evenhanded application of this requirement effectively forecloses any conclusion that the petition was objectively baseless as a matter of law.[4]

Finally, Louisiana Wholesale does not dispute the fact that the FDA's confidential treatment of ANDAs increases the necessity for petitioning protection. Motion at 12-13. The risk of treble damages for misjudging the contours of an ANDA, would chill the very petitioning activity that the *Noerr-Pennington* doctrine is designed to protect. Nor does Louisiana Wholesale dispute that exposing petitioners to antitrust liability could deprive the FDA of valuable sources of information about drug safety and efficacy. *Id.* This is a concern the Court cannot dismiss lightly. *Noerr-Pennington* immunity is vital to ensuring the FDA's mission to safeguard the public from unsafe and/or ineffective medications.

In short, Louisiana Wholesale has failed to meaningfully address the fact and application of standards governing *Noerr-Pennington* immunity to the allegations in the Complaint and the administrative record, or to rebut Aventis' showing that its petitioning conduct is immune from antitrust liability as a matter of law. The complaint should be dismissed for this reason alone.

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[4] Further, Louisiana Wholesale's *post hoc* analysis of what Aventis should have known about ANDAs seeking approval for some but not all dosages of a branded drug, Opp'n at 12-13, ignores one critical fact and contradicts another. First, the other drugs identified in the FDA's response to the petition—including two manufactured by Aventis—did not include loading doses, which raise particular safety and efficacy concerns. Indeed, Kali Laboratories recognized this distinction and suggested the very remedy that the FDA ultimately adopted: to permit the Generic Manufacturers to refer to the Arava 100mg loading dose in their labels. Motion Exh. 3 at 2. Second, the other Generic Manufacturer who commented on the petition found the petition to be credible on its face. Motion Exh. 4. This simple, judicially-noticeable fact directly contradicts Louisiana Wholesale's assertion that "no reasonable pharmaceutical manufacturer could have expected the Petition to succeed on the merits," Opp'n at 10, and compels the conclusion that "an objective litigant could conclude that the [petition was] reasonably calculated to elicit a favorable outcome, the [petition] is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail." *PRE*, 508 U.S. at 60.

II. Louisiana Wholesale Lacks Antitrust Standing to Sue for Wholly Speculative and Derivative Injuries

Louisiana Wholesale has not pleaded any facts supporting its speculative conclusion that "if the Petition had not been filed, the ANDAs would have been approved (and on the market) months earlier." Compl. ¶¶ 7, 62; Opp'n at 7. As the Supreme Court held in *Twombly*, "[f]actual allegations [in a complaint] must be enough to raise a right to relief above a speculative level . . . on the assumption that all the allegations in the complaint are true." *Bell Atlantic Corp. v. Twombly*, ___ U.S. ___, 127 S. Ct. 1955, 1965 (2007).

The Complaint, which rests on blunderbuss allegations about branded drug manufacturers and citizen petitions generally, (*see* Compl. ¶¶ 38-43; Opp'n at 4), and an allegation that Aventis should be tainted with guilt by association consequently, (*see* Compl. ¶¶ 54-58; Opp'n at 6-7), clearly fails the *Twombly* test. These conclusory allegations are reason enough to dismiss the complaint. In addition, these allegations are *affirmatively rebutted* by the administrative record, which clearly demonstrates that (1) the Generic Manufacturers were amending their ANDAs while the citizen petition was pending, presumably to address concerns raised in the citizen petition or some other fundamental flaws, *see* Motion Exh. 7; and (2) the ANDAs were approved two months *faster* than the FDA's then-average of 20 months, *see* Motion at 3 n.2.[5]

In the absence of specific and *supportable* allegations that the Generic Manufacturers were poised and ready to market generic leflunomide, and that the FDA would have approved their applications more quickly but for the citizen petition, Louisiana Wholesale cannot state a claim that Aventis' petitioning conduct caused it any harm. *See City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 268 (3d Cir. 1998) (holding that a "plaintiff cannot be injured in fact

[5] Louisiana Wholesale does not contest these facts, and argues instead that in its "counsel's experience litigating many pharmaceutical antitrust cases, amendments to ANDAs are common up until, and even after, the date of FDA approval." Opp'n at 16. Needless to say, the unsupported and self-serving representations of counsel cannot displace judicially-noticeable facts in the administrative record.

by private conduct excluding him from the market" when a statutory or regulatory scheme prevents competitive entry) (citation omitted).[6]

As the First Circuit observed in *DM Research, Inc. v. College of American Pathologists*, 170 F.3d 53 (1st Cir. 1999), the "price of entry, even to discovery, is for the plaintiff to allege a *factual* predicate concrete enough to warrant further proceedings, which may be costly and burdensome. Conclusory allegations in a complaint, if they stand alone, are a danger sign that the plaintiff is engaged in a fishing expedition." *Id.* at 55. The Complaint, regulatory framework, and administrative record here very clearly signal that Louisiana Wholesale hopes to survive the Motion in order to exact the substantial cost and burden associated with antitrust discovery—the very danger against which the Supreme Court cautioned when it affirmed the dismissal of the Twombly complaint. *Twombly*, 127 S. Ct. at 1967.

Louisiana Wholesale also lacks antitrust standing because it is not an "efficient enforcer" of the antitrust laws. Louisiana Wholesale blithely asserts that it is a "direct purchaser" and as such is entitled to bring a Sherman Act claim for petitioning conduct Aventis allegedly directed toward the Generic Manufacturers. Opp'n at 17. But the simple fact that Louisiana Wholesale is a "direct purchaser" of allegedly monopolized goods does not mean that it is an appropriate plaintiff for purposes of all Sherman Act claims. Indeed, the Second Circuit has frequently limited the ability of particular plaintiffs—purchasers or otherwise—to sue under the Sherman Act, particularly where a defendant allegedly exercises the restraint on trade against another party.

[6] Remarkably, Louisiana Wholesale contends that this argument should fail because Aventis did not identify a particular law precluding the marketing of generic leflunomide. Opp'n at 16 n.8. That law is the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA"), which was clearly identified in the Motion at 2-3. The FDCA precludes any person from "introduc[ing] or deliver[ing] for introduction into interstate commerce any new drug" unless and until that person receives FDA approval to do so. 21 U.S.C. § 355(a). Courts interpreting Section 355(a) in the context of antitrust claims have routinely held that any alleged harm to competition that flows from this requirement cannot constitute a violation of the antitrust laws. *See, e.g., In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 791-92 (8th Cir. 2006) (affirming dismissal of claim that defendants conspired to prevent the importation of prescription drugs from Canada into the United States, and noting that any absence of competition was the result of the FDCA, not the defendants' actions).

Thus, in *Paycom Billing Services, Inc. v. MasterCard International, Inc.*, 467 F.3d 283 (2d Cir. 2006), the Second Circuit concluded that a merchant purchaser of defendant's services lacked standing to sue because the defendant's alleged restraint of trade was directed toward competing bankcard networks, not toward merchant purchasers like the plaintiff. *Id*. at 293. So holding, the court applied four "efficient enforcer" factors to determine whether the plaintiff bringing suit suffered direct harm, thereby incentivizing it to enforce the antitrust laws for something more than a speculative and duplicative claim. *See* Motion at 18-19. Louisiana Wholesale pays lip service to the efficient enforcer factors, Opp'n at 18, but does not dispute that it did not suffer direct harm from Aventis' petitioning conduct.

Nor can Louisiana Wholesale distinguish *Paycom* and *Laborers Local 17 Health and Benefit Fund v. Phillip Morris Inc.*, 191 F.3d 229 (2d Cir. 1999)—the controlling authority for purposes of this case—by arguing that the plaintiffs in those cases were indirect purchasers who did not have standing to pursue Sherman Act claims. Opp'n at 18 & n.10. In fact, *Paycom* and *Laborers Local* involved the same problem that plagues Louisiana Wholesale here: the plaintiff's putative injuries are wholly derivative of those allegedly suffered by the parties directly within the zone of the allegedly anticompetitive conduct. Accordingly, this Court should follow the same path as the *Paycom* and *Laborers Local* courts and dismiss the complaint.

III. Louisiana Wholesale Has Failed to Substantiate Its Self-Serving and Self-Limiting Allegations Concerning the Relevant Market

Monopolization claims—even those predicated on direct evidence of market power—must be proven with respect to a relevant market. In this case, Louisiana Wholesale has alleged that the relevant market is limited to leflunomide. But its legal arguments do not square with the law and its factual allegations are belied by the citizen petition attached to the Complaint, which lists numerous other drugs that are functionally equivalent to leflunomide.

First, there is no merit to Louisiana Wholesale's argument that it need not define the relevant market because it has alleged direct evidence of monopoly power. Opp'n at 19. The Second Circuit has clearly held that a plaintiff "cannot escape proving her claims with reference to a particular market even if she intends to proffer direct evidence of controlling prices or excluding competition." *Heerwagen v. Clear Channel Commc'ns*, 435 F.3d 219, 229 (2d Cir. 2006).[7]

Second, Louisiana Wholesale's conclusory and self-serving allegations that generic leflunomide was cheaper than Arava and that the price of Arava dropped after generic entry do not define a market. Compl. ¶¶ 73, 76 A price decrease in response to generic sales does not mean that prices before generic entry were supracompetitive, as it is just as likely that generic drug prices were lower due to lower generic manufacturing costs. *Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 500 (2d Cir. 2004) (holding decrease in price was "at best ambiguous" evidence of monopoly power). Moreover, ambiguous allegations that are as consistent with pro-competitive behavior as with anticompetitive behavior are insufficient to withstand a motion to dismiss. *Twombly*, 127 S. Ct. at 1965 (holding "[f]actual allegations must be enough to raise a right to relief above the speculative level").

In a directly analogous case, the court in *In re Remeron Direct Purchaser Litigation*, 367 F. Supp. 2d 675 (D.N.J. 2005), rejected an attempt to define the relevant market based on evidence of decreased prices in a post-generic world because "Plaintiffs' approach, if applied beyond this case, would render most brand name pharmaceutical companies as *per se*

[7] Louisiana Wholesale cites *FTC v. Indiana Federation of Dentists*, 476 U.S. 447 (1986) for the proposition that a relevant market analysis is not necessary if direct evidence of monopoly power exists. Opp'n at 19. But that case involved a Section 1 claim, as to which market power is not an independent element. *Todd v. Exxon Corp.*, 275 F.3d 191, 206-07 (2d Cir. 2001). In contrast, market power in a relevant market is an essential element of a Section 2 claim; consequently, it is always "necessary to appraise . . . the relevant market for the product involved." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 455-56 (1993). The other Second Circuit cases Louisiana Wholesale cites are similarly inapposite, since they stand for the unremarkable proposition that monopoly power may be proven with direct evidence of monopoly power or with indirect evidence of market share.

monopolists prior to generic entry." *Id*. at 683. The *Remeron* court relied on the Supreme Court's holding in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), that monopoly power cannot automatically be considered conferred upon a patent holder without more evidence of market power. The court thus rejected plaintiff's effort "to use nothing beyond the typical reality facing patent holders in the pharmaceutical market (high brand name prices relative to that of generic entrants) as the sole basis for inferring that the brand name patent holder has monopoly power." *Remeron*, 367 F. Supp. 2d at 684.

Here, as in *Remeron*, market power cannot be inferred from the mere fact that Aventis was legally entitled to a period of marketing exclusivity following the FDA's approval of the Arava NDA. The only facts Louisiana Wholesale alleges to support its conclusory allegation of supracompetitive prices are the same facts found insufficient as a matter of law in *Geneva* and *Remeron—i.e.*, that the newly introduced drug was cheaper than the existing drug. The Complaint is completely devoid of any allegations that Aventis' price-cost margin for Arava was "abnormally high," *Geneva*, 386 F.3d at 500, and relies on a document identifying numerous other drugs to which consumers could have turned if Aventis sought to artificially increase the price of Arava. Without factual allegations to support the conclusion that Aventis engaged in supracompetitive pricing, Louisiana Wholesale's molecule-specific (and self-limiting) relevant market allegation must fail.[8]

Louisiana Wholesale's argument that price elasticity must be considered in addition to functional interchangeability when defining a relevant market is a red herring. While this

[8] The best support that Louisiana Wholesale can come up with for its argument that relevant markets are "routinely" limited to the drug's constituent molecule is an ABA newsletter reflecting the opinion of the expert plaintiffs hired in *Geneva*. But the court in *Geneva* did not hold that the relevant market equaled the molecule; rather, the court found the relevant market consisted of the generic (but not branded) drugs due to factors including inelastic demand, price differences, and varying distribution chains. 386 F.3d at 497-98. Louisiana Wholesale also cites a handful of cases in which the courts declined to consider the relevant market issue, observed in dicta that the relevant market *might* be limited to the drug and its generic equivalents, or limited the relevant market to a brand name drug and its generic equivalents due to unique market characteristics indicating that the drug constituted a market separate from other drugs used to treat the same conditions. These cases do not stand for the categorical proposition that a relevant market should be limited a drug's component molecule.

statement of black-letter law is correct, the Complaint is utterly devoid of allegations concerning price sensitivity (or a lack thereof) between leflunomide and other disease-modifying anti-rheumatic drugs ("DMARDs") or unique customer characteristics indicating that patients would not switch to other DMARDs in the face of a price increase for leflunomide. To the contrary, as noted above, the Complaint and its attachments reveal numerous other functionally substitutable products with prices comparable to or cheaper than leflunomide.

Finally, Louisiana Wholesale attempts to salvage its Complaint by arguing that the scope of the relevant market is a factual issue that cannot be decided on the Motion. In order to survive a motion to dismiss, however, a complaint must contain allegations that are not internally inconsistent and that support a cause of action. Louisiana Wholesale's relevant market definition is belied by the citizen petition, and while the Court must give the plaintiff the benefit of all well-pled factual allegations, it may not give Louisiana Wholesale the benefit of facts it did not plead or disregard facts contradicted by the administrative record. *See Twombly,* 127 S. Ct. at 1974 (dismissing complaint for failure to plead "enough facts to state a claim to relief that is plausible on its face"). Accordingly, the Complaint must be dismissed for failure to adequately plead a relevant market.

Respectfully submitted,

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Dated: November 15, 2007

CERTIFICATE OF SERVICE

I, Rosanna K. McCalips, certify that the foregoing Reply Memorandum of Points and Authorities was served on November 15, 2007, on the counsel listed below in the manner(s) indicated below:

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